REMARKS/ARGUMENTS

In the Office Action of August 10, 2007, the Examiner rejected claims 1-14 of the above-identified application under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0085950 to Robitaille et al. in view of U.S. Patent No. 4,764,351 to Hennebert et al. The Applicant has considered the Examiner's rejection but respectfully requests the Examiner to reconsider and withdraw the rejection.

In general, the test for patentability under 35 U.S.C. § 103 is whether the differences between the claimed subject matter, considered as the whole, and the prior art would have been obvious at the time the invention was made. *Graham v. John Deere Co.*, 381 U.S. 1, 148 USPQ 459 (1966). There must be **an apparent reason to combine the known elements** in the fashion claimed by the patent at issue. *KSR International Co. v. Teleflex Inc.*, 127 U.S.1727, 1732 (2007). As will be explained more fully below, neither Robitaille et al. nor Hennebert et al. teach or suggest purging condensed water from the sterilization chamber between separate sterilization cycles.

The Robitaille et al. reference, the Applicant's own reference, deals with ozone sterilization methods. When considered against conventional sterilization methods, ozone sterilization shows the most promise as a quick, effective and safe sterilization procedure. However, ozone on its own is not reliable. In order to achieve reliable sterilization, it is known that there must be water present, and in particular, a high humidity level. See paragraph 0006 of Robitaille et al. As discussed in Robitaille et al., even the extremely high humidity level of 85% is not consistently reliable and a preferred humidity for reliability is above 90%, and preferably 100%. See paragraph 0016 of Robitaille et al.

The Applicant respectfully submits that the Robitaille et al. reference represented a substantial breakthrough in realizing the potential of ozone sterilization by the realization that the application of a reduced pressure step provided an effective means to achieve the high humidity levels needed. Thus, in Robitaille et al., it is disclosed that water is evaporated from a water reservoir by means of a vacuum so that the water is able to "boil" at around ambient temperature (preferably in the range of 25 to 35°C), and thus at a much lower temperature than the normal boiling point of 100 °C. See, for example, paragraph 0086 of Robitaille et al. As previously noted, the Robitaille et al. process was developed by the present Applicant. However, the Robitaille et al. apparatus met with unforeseen problems, as outlined on page 4 of the present specification. Although available to the public, the teachings of Robitaille et al. did not lead to any obvious resolution of these problems.

As mentioned in Robitaille et al., a layer of condensed water on the surface of an item to be sterilized will provide a barrier to the ozone and thus a barrier to effective sterilization of the item. See paragraph 0011 of Robitaille et al. This condensation problem is discussed in some detail in paragraph 0050 of Robitaille et al. In that section, it is pointed out that, in order to achieve efficient and reliable sterilization, the sterilization process should operate at a relative humidity as close to 100% as possible. It is pointed out that such high levels of humidity create "additional challenges associated with unwanted condensation on articles to be sterilized and/or components of the sterilization apparatus which are exposed to the sterilization atmosphere". It is quite clear that, according to the teachings of the reference, the way to resolve these challenges is by temperature equalization. The above-quoted passage is immediately followed by the statement:

> "In particular, it has been found that even slight differences in temperature between the atmosphere in the sterilization chamber and the articles to be sterilized or the atmosphere and components of the apparatus will trigger significant condensation when the relative humidity of the chamber is close to saturation. However, since it is desired for maximum efficiency of the ozone

sterilization to operate as closely as possible to saturation and to avoid condensation on the articles to be sterilized, ***at least prior to ozone injection***, such temperature differences should be avoided as much as possible" (emphasis added).

Thus, according to the reference, the problems associated with condensation are resolved by temperature equalization prior to the sterilization process. In fact, throughout this entire reference, this is the only solution suggested to the problem of condensation. Thus, according to this reference, condensation problems are resolved by careful temperature equalization ***prior*** to the sterilization process. For example, in paragraph 0030 of Robitaille et al., the document sets forth that temperature equalization is effected "prior to commencement of the actual sterilization with ozone." This point is further reflected in the method steps claimed in Robitaille et al. including "equalizing the temperature of the article and an atmosphere in the sterilization chamber." The importance of this step, as disclosed through the Robitaille et al. reference, is to avoid condensation problems. Additionally, the importance of the temperature equalization is illustrated in paragraph 0083 of Robitaille et al. which states that, because of the high level or relative humidity, and to prevent condensation on the inner surfaces of the chamber, the bottom of the chamber, the door and water vapor piping are all heated.

Nowhere does Robitaille et al. suggest any other solution to the problem of condensation. In fact, the Examiner has conceded that Robitaille et al. is silent with respect to removing condensation during the sterilization cycle between successive exposures to humidified ozone. See pages 2-3 of the Office Action.

With respect to claims 2-4 and 11-13, the Examiner has conceded that Hennebert et al. does not teach how condensate is purged. However, the Examiner points to Robitaille and states that the reference "already discloses a method of removing humidity at the end of the sterilization cycle by flushing with repeated pulses of oxygen." The Applicant respectfully disagree with this assertion.

Although paragraph 0047 of Robitaille et al. implies that single cycle sterilization is more efficient, a multiple cycle sterilization process is described in paragraphs 0060-0067. The importance of the temperature equalization phase with respect to the multi-cycle process is stated in paragraph 0061. In this passage it is stated that "after the sterilization cycle is completed a ventilation phase is commenced". The ventilation phase is the final step of removing any residual reactants such as residual ozone. There is no suggestion here of any additional step between sterilization cycles to remove condensation. In paragraph 0065 of Robitaille et al., details of the multi-cycle process continue stating that, after the sterilization state of the first cycle, in an optional second step, the pressure level is raised using oxygen as a filling gas. This raised pressure level is maintained for about 20 minutes, then the vacuum is reapplied and the next cycle is started. Regarding this passage, there is no mention or indication of any step to remove condensation. To remove condensation, there would need to be a flushing of the apparatus with some gas for that purpose. That is simply not the case in Robitaille et al. where the apparatus is filled with oxygen and maintained in that state for 20 minutes. This is clearly not a flushing step, and would not remove "any condensed water" as required by the present claims.

A proper rejection under 35 U.S.C. § 103 cannot be based on hindsight knowledge of the invention under consideration for the sole basis of attempting to meet the recitations of the claims. *Environmental Designs, Ltd. v. Union Oil Co. of Cal.* 218 USPQ 865, 870 (1983). In contrast to the applied prior art references, the present application recognizes that condensation after a first or subsequent sterilization cycles poses a real problem. This problem was unexpected because, as explained above, it was considered by the Applicant's own prior art, which is relied upon by the Examiner, that temperature equalization before humidification removed condensation problems. Thus, in the present application, it has been discovered that condensation is not just a problem during the humidifying step, but presents a real problem after the ozone sterilization step and before the start of the next sterilization cycle. As is stated on page 4 of the present application, although the repeated sterilization method described in Robitaille et al.

(which is clearly referenced on page 3 of the present application) has proven effective, problems were encountered.

With respect to sterilizing hospital equipment, for example, it is critical that a sterilization process is successful. Thus, the combination of ozone concentration and relative humidity are constantly monitored and if the measured values indicate that sterilization may be compromised, the whole process is aborted and the procedure restarted from the beginning. The inventors of the present application were looking to resolve such problems. The investigative process which led to their conclusions is mentioned on pages 5 and 6 of the present application. More specifically, the inventors realized that the presence of some condensation, even trace amounts, at the start of a subsequent sterilization cycle could result in "cold spots" which would in turn induce condensation in the ***subsequent*** humidification step. As a result of their efforts, it was considered that condensation occurring ***between*** separate sterilization cycles may have been the cause of sterilization problems and the inventors subsequently confirmed this. Before the inventors' realization, it was believed that simply relying on temperature equalization (as used in the first step) would be sufficient to eliminate the possibility of condensation in the subsequent humidification step. Therefore, although with hindsight the step of removing any condensed water between sterilization steps could prove beneficial, before the discovery that led to this invention, there was no reason to believe that there would be any condensation, or at least not enough to affect subsequent sterilization cycles since great care was taken in the temperature equalization step to avoid just that possibility. In accordance with the present invention, inserting an additional step in the sterilization process reduces the number of times the sterilization procedure must be aborted and improves the effective sterilization of instruments. The Applicant respectfully submits that Robitaille et al. does not disclose any step of removing condensation between cycles in a multiple sterilization process, nor was such a step obvious at the time of the invention.

With respect to the Hennebert et al. reference, the Applicant respectfully submits that this reference is far afield from the present invention. As stated by the Court of Appeals for the Federal Circuit, "[i]t is necessary to consider 'the reality of the circumstances, in other words, common sense--in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor." In re Oetiker, 977 F.2d 1443, 1447 (Fed. Cir. 1992), (quoting In re Wood, 599 F.2d 1032, 1036 (C.C.P.A. 1979)). Further, if a reference disclosure has a different purpose from the claimed invention, the inventor would accordingly have had less motivation or occasion to consider it then they would if the reference relates to the same problem. Id. citing In re Clay, 966 F.2d 656, 659-60 (Fed. Cir. 1992).

Hennebert et al. is essentially concerned with formaldehyde sterilization. Although the Hennebert et al. indicates the possibility of other sterilization agents, no other agents are detailed. Every reference in Hennebert et al. refers to formaldehyde. In formaldehyde sterilization processes, as Hennebert et al. teaches, it is common to use steam. One of the functions of the steam is as a form of heat or to control the temperature. However, another function is recognized: that the sterilization is more effective when certain bacteria are moistened. Formaldehyde can be effective even when used under dry conditions. Certainly, the humidity in formaldehyde sterilization is by no means critical. Indeed, the Hennebert et al. teachings appear to suggest that the purpose of the steam is simply to increase the temperature. See column 8, lines 16-18 stating "[s]team flow is controlled by valve 18, which is regulated so that the temperature in chamber 1 reaches the chosen sterilization temperature." This is in complete contrast to ozone sterilization in accordance with the invention in which ozone is not an effective sterilant unless the humidity is carefully controlled and kept at extremely high values. There is no equivalent in formaldehyde sterilization to the careful control of humidity which is required in the ozone sterilization of the invention. Thus, a person skilled in the art, looking for a solution in an ozone sterilization process, would have no reason and no motivation to look for answers in formaldehyde sterilization.

Based on the above, it is requested that the prior art rejections be withdrawn the claims allowed and the application passed to issue. If the Examiner should have any additional concerns regarding the allowance of the application that can be readily addressed, she is cordially invited to contact the undersigned at the number provided below in order to further expedite prosecution.

Respectfully submitted,

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